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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,068	08/27/2003	Joseph L. Mark	65937-0037	4645

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EXAMINER	
SOLANKI, PARIKHA	

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,068	MARK ET AL.	
	Examiner	Art Unit	
	Parikha Solanki	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/27/03,12/08/03,11/16/05,12/16/05,1/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :8/27/03,2/27/04,4/12/04,4/20/05,1/3/06.

DETAILED ACTION

Claim Objections

1. Claims 33 and 34 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 33 and 34 recite dependence upon the methods of claims 1 and 7, respectively, but claims 1 and 7 do not recite any such methods. For the purposes of examination in the remainder of this office action, it is assumed that Applicant intended to use the word "system" in place of the word "method" in claims 33 and 34. Applicant is required to amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form, or cancel the claims from the application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "relatively low artifact generating" in claim 19 is a relative term which renders the claim indefinite. The term "relatively low artifact generating" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is suggested that the specification and or/claim should be amended to explicitly establish the criteria that determine whether a material is low artifact generating.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-14 and 18-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Werne (US Pat. No. 5,782,764).

Regarding claims 1-11, Werne ('764) provides an invasive medical instrument for use in an MRI imaging system, wherein a portion of the instrument is marked with an MRI-visible contrast agent (col. 6 lines 55-58). Specifically, the instrument is comprised of a marker stylet, equivalent to a target confirmation device, that fits removably within a biopsy needle or a catheter (col. 7 lines 6-11). Werne ('764) discloses that the MRI-visible material is a chamber, equivalent to a band, disposed at the distal end of the marker stylet (Fig. 1, col. 9 lines 61-64).

Regarding claims 12-14, Werne ('764) discloses a medical system which includes a marker stylet, over which a cannula is inserted (col. 10 lines 53-66, col. 11 lines 21-24). Werne ('764) discloses that the cannula is positionable within the patient's body after removal of the marker stylet (col. 10 line 66 – col. 11 line 4). Werne ('764) discloses that the system may include a needle-shaped device with a sharp tip at the distal end such as a biopsy needle, which is capable of piercing tissue as described in claim 13 of the instant application (col. 9 lines 42-44, col. 10 lines 53-58). Werne ('764) further discloses that the inner lumen of the outer cannula may be in communication with a fluid conduit (col. 11 lines 2-4, Figs. 2 & 3).

Regarding claims 18-25, 36-39 and 43-48, Werne ('764) anticipates the invention of claim 12 as described above. Werne ('764) further discloses that the marker stylet contains material that is visible during MRI imaging, such as a Gd-DTPA, which is known in the art to reduce the occurrence of artifact in medical MR imaging (col. 11 lines 28-29 & 32-33). Werne ('764) discloses that the instrument is made of a carbon-fiber composite material such that it does not unacceptably obscure or distort the image of the object (col. 6 lines 46-50). It is known in the art that carbon-fiber composites have very low electrical conductivity, and as such will appear void on an MR image. The instrument of Werne ('764) has a cutting element with a tissue-receiving opening for accepting tissue from the target site (Figs. 9 & 10). The proximal end of the instrument of Werne ('764) is equivalent to a handpiece as described in the instant application. While Werne ('764) does not explicitly disclose the length of the marker stylet, it is known in the art that surgical stylets must be approximately the same length as the cannula or catheter in which they are disposed, and as such it is implied that the marker stylet of Werne ('764) is approximately the same length as the distance between the tissue receiving opening and the handpiece of the biopsy needle. It follows that, since the targeting band is disposed at the distal end of the marker stylet, the distance between the proximal end of the stylet and its marker band is approximately equivalent to the distance between the center of the tissue

receiving opening and handpiece of the biopsy needle. Werne ('764) discloses that the distal end of the marker stylet is inserted into the target tissue site, such that it must be the same length as that of the cutting element (col. 10 line 64-65).

Regarding claims 33-35, Werne ('764) discloses an obturator with a tissue receiving opening, the obturator operable for insertion into and rotation within an outer cannula (Figs 9 & 10). Werne ('764) shows that the obturator is used for tissue resection (Figure 9).

Regarding claims 26-32, 41, 42 and 49, Werne ('764) discloses a method of using the medical system consisting of a cannula, a marker stylet, and an obturator rotatable within the cannula, the method comprising the steps of inserting the marker stylet and cannula into the patient, producing an image containing the stylet and the target tissue, removing the marker stylet, inserting an obturator within the cannula after stylet removal, and subsequently resecting a tissue sample for biopsy with the obturator (col. 7 lines 41-47, col. 10 line 61 – col. 11 line 11). It is known in the art to ablate tumors immediately following during a biopsy procedure, and that ablation catheters are deliverable within cannulae such as the one described by Werne ('764). The practice of aspirating biological tissue prior to resection during biopsy is also well known in the art.

Regarding claim 40, Werne ('764) shows that the length of the target confirmation device is approximately equal to the length of the cannula (Fig. 8).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 15 – 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Werne ('764) in view of Laird (US Pat. No. 6,276,661). Werne ('764) discloses a medical system meeting all the limitations of the present invention as described above, with the exception of a hemostasis valve. Werne ('764) is silent as to whether or not such a valve is present in the system. Laird ('661) discloses a pressure-actuated introducer valve, equivalent to a directional valve and a hemostatic valve, to be used with minimally invasive surgical implements such as guidewires and endovascular catheters (Abstract lines 1-4, Figure 1). The valve of Laird ('661) is

further operable to engage an interface of the outer cannula with an interface of the target confirmation device as described in the instant application (Figure 4). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the medical system of Werne ('764) to include the hemostasis valve of Laird ('661) on the proximal end of the catheter/stylet assembly for the purpose of preventing outflow of bodily fluids such as blood when the assembly is inserted into the patient during a surgical procedure.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hurtak (WO 98/55016) discloses a related guidewire with MRI-visible contrast bands. McIvor (US Pat. No. 6,213,988) discloses a related hemostatic clip apparatus for use with a catheter/introducer system. Van Bladel (US Pat. No. 6,494,844) discloses a related cannula biopsy system including a hemostatic element, and also discusses known methods of tumor ablation during biopsy.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha Solanki whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Parikha Solanki
Examiner – Art Unit 3737

BRIAN L. CASLER
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